DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 9 2001

Re: Xenical®
Docket No.: 00E-1413

The Honorable Q. Todd Dickinson
Director of U.S. Patent and Trademark Office
Commissioner for Patents
Box Pat. Ext.
Washington, D.C. 20231

Dear Director Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,598,089, filed by HLR Technology Corporation, under 35 U.S.C. section 156. We have reviewed the dates contained in the application and have determined the regulatory review period for Xenical®, the human drug product claimed by the patent.

The total length of the regulatory review period for Xenical® is 3,969 days. Of this time, 3,091 days occurred during the testing phase and 878 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 12, 1988.

   The applicant claims June 24, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 12, 1988, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: November 27, 1996.

   The applicant claims November 26, 1996, as the date the new drug application (NDA) for Xenical® (NDA 20-766) was initially submitted. However, FDA records indicate that NDA 20-766 was submitted on November 27, 1996.

3. The date the application was approved: April 23, 1999.

   FDA has verified the applicant's claim that NDA 20-766 was approved on April 23, 1999.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: George W. Johnston
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